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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,637	03/07/2002	Lester David Michels	30895B/C1	1332

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

MADSEN, ROBERT A

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,637

Applicant(s)

MICHELS ET AL.

Examiner

Robert Madsen

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. The response filed May 15,2004 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoi et al. (US 565895) in view of Gans et al. (US 4025650) and Furia. See the Office Action mailed November 10,2003.
4. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gans et al. (US 4025650) in view of Aoi et al. (US 565895). See the Office Action mailed November 10,2003.

Response to Arguments

5. Applicant's arguments filed May 15,2004 have been fully considered but they are not persuasive.
6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

7. Regarding claims 1-12, Aoi teaches an enteral composition and teaches the composition may comprise preservatives such as esters of p-hydroxybenzoic acid (i.e. parabens), salts of benzoic acid, and salts of sorbic acid. Although, Aoi clearly teaches the genus of the various preservatives, Aoi fails to teach the species and quantities recited in claim 1. Thus the primary references already recognizes that parabens, salts of benzoic acid, and salts of sorbic acid are effective enteral composition preservatives. Applicant argues that there is no motivation to combine Gans with Aoi because Gans does not teach a *complete* solution and there is no expectation of success. However, in applicant's admission of the prior art, it is proteins, starch and other components, which build up around the interior of a feeding tube that result in microbial problems. Although Gans fails to teach the exact formulation of Aoi, Gans adds the particular type and amount of paraban and salts of sorbic or benzoic acids for the same purpose as Aoi: preserving nutritional formulas comprising protein and carbohydrates fed to a patient with a feeding tube. Furia, is relied on as further evidence of the conventionality of the particular effective amount of each paraben, as well as the cumulative effect of adding both benzoates and parabens. Thus, not only does Gans suggest the particular combination of specific preservatives that fall within the genus of preservatives taught by Aoi for the same purpose, but Furia provides motivation for utilizing such a combination in that the antimicrobial effects are cumulative.

Regarding claims 13-15, Gans teaches a method of inhibiting the growth *Aspergillus niger*, *Candida albicans*, *Enterobacter cloacae*, *Staphylococcus aureus*, and *Lactobacillus delbruekii* because Gans teaches *preserving* a nutritional solution. Obviously, the solution of Gans would not be "preserved" if the growth of *Aspergillus niger*, *Candida albicans*, *Enterobacter cloacae*, *Staphylococcus aureus*, or *Lactobacillus delbruekii* had occurred. Gans teaches preserving using the recited preservatives in the recited quantities. Gans only differs in teaching a *complete* nutritional solution. As noted by Gans, a *complete* solution would include protein, carbohydrates, and fat (Column 2, lines 35-58), but Gans removes the fat for the particular formulation for providing nutrients to anorexics. It is notoriously well known that a higher water content in combination with protein and carbohydrates is more susceptible to microbial problems than one of lower water content and higher fat. Thus, if the preservative disclosed by Gans were effective for a higher water content solution one would expect them to be just as effective in a lower water content/higher fat solution. Aoi teaches it is known to stabilize complete enteral solutions for cancer patients with parabens and salts of both sorbic acid and benzoic acid, which are the same preservatives taught by Gans. Thus, to modify the method taught by Gans and include additional the ingredients found in Aoi (such as fat) to arrive an enteral solution would depend on whether it was for anorexics or cancer patients, since one would expect the preservative cocktail taught by Gans would be effective in a composition that would comprise protein, carbohydrates, and fats.

8. In response to applicant's argument that none of the references teaches the synergistic effect of parabens/sorbate/benzoate, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Aoi suggests all three as useful preservatives for enteral solutions, while Gans teaches the combination of parabens/sorbate/benzoate as an effective preservative for protein/carbohydrate containing nutritional solutions used for feed tubes. It is noted that Furia does recognize the synergistic effect of paraben and benzoates.

Conclusion

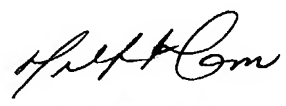
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402. The examiner can normally be reached on 7:00AM-3:30PM M-F.
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Madsen
Examiner
Art Unit 1761




MILTON I. CANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700